Tuberculosis *(Mycobacterium tuberculosis)*

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1) THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Tuberculosis is a communicable disease caused by the *Mycobacterium tuberculosis* complex, which includes *Mycobacterium tuberculosis* and *Mycobacterium africanum*, both primarily from humans, and *Mycobacterium bovis* from cattle.

B. Clinical Description and Laboratory Diagnosis

Tuberculosis is a mycobacterial disease, which starts as a pulmonary infection. Early lung lesions commonly heal and leave no residual changes except occasional pulmonary or tracheobronchial lymph node calcifications. In approximately 5% of apparently normal hosts and as many as 50% of persons with advanced HIV infection, the initial infection may progress directly to pulmonary, miliary, meningeal or other extrapulmonary involvement. Serious outcomes of initial infection are more frequent in infants, adolescents, young adults and the immunosuppressed.

Extra-pulmonary TB occurs less commonly than pulmonary TB. Children and persons with immunodeficiencies, such as from HIV infection, have a higher proportion of extrapulmonary TB, but pulmonary disease remains the most common type of TB disease worldwide, even in those more susceptible groups. TB disease may affect any organ or tissue such as the lymph nodes, pleura, pericardium, kidneys, bones and joints, larynx, middle ear, skin, intestines, peritoneum and eyes.

Progressive pulmonary TB arises from exogenous reinfection or endogenous reactivation of a latent focus remaining from the initial infection. If untreated, about half the patients will die within 5 years, a majority of these within 18 months.

Clinical status is based mainly on the presence or absence of tubercule bacilli in the sputum and findings on chest radiographs. Abnormal radiographic densities indicative of pulmonary infiltration, cavitation and fibrosis can occur before clinical manifestations. Fatigue, fever, night sweats and weight loss may occur early, while localizing symptoms of cough, chest pain, hemoptysis and hoarseness become prominent in advanced stages.

A presumptive diagnosis of active TB disease is made by demonstration of acid-fast bacilli in stained smears from sputum or other body fluids; a positive sputum smear justifies the initiation of anti-tuberculosis therapy. The diagnosis is confirmed by isolation of the organisms of the *Mycobacterium tuberculosis* complex on culture. This also permits the determination of the drug susceptibility of the infecting organism. However, in the absence of bacterial confirmation, active TB disease can be presumed and anti-tuberculosis treatment initiated if there is strong clinical evidence of an ongoing disease process by histologic or radiologic studies in a patient with a positive tuberculin skin test.

C. Reservoir

Primarily humans, rarely primates; in some areas, diseased cattle, badgers, swine, and other mammals are infected.

D. Modes of Transmission

Exposure to tubercule bacilli in airborne droplet nuclei produced by people with tuberculosis of the respiratory tract (primarily pulmonary or laryngeal) during expiratory efforts, such as coughing, singing or sneezing. Health care workers may be exposed during medical procedures such as bronchoscopy, autopsy or intubation. Laryngeal tuberculosis is highly contagious. Prolonged close exposure to an infectious case

may lead to infection of contacts. Direct invasion through mucous membranes or breaks in the skin may occur but is extremely rare. Bovine tuberculosis occurs from exposure to tuberculous cattle, usually by ingestion of unpasteurized milk or dairy products and sometimes by airborne spread to farmers and animal handlers. Except for rare situations where there is a draining sinus, extrapulmonary tuberculosis (other than laryngeal) is generally not communicable.

E. Incubation Period

From infection to demonstrable primary lesion or significant tuberculin reaction, about 2-10 weeks. While the subsequent risk of progressive pulmonary or extrapulmonary TB is greatest within the first year or two after infection, latent TB infection persists for a lifetime. HIV infection appears to increase the risk greatly and shorten the interval for the development of TB disease.

F. Period of Communicability or Infectious Period

Theoretically, as long as viable tubercule bacilli are being discharged in the sputum. Some untreated or inadequately treated patients may be sputum positive intermittently for years. The degree of communicability depends on the number of bacilli discharged, the virulence of the bacilli, adequacy of ventilation, exposure of the bacilli to sun or UV light, and opportunities for their aerosolization by coughing, sneezing, talking or singing, or during high risk medical procedures such as autopsies, intubations or bronchoscopies. Effective antimicrobial chemotherapy taken as prescribed usually eliminates communicability within a few weeks, but non-infectiousness must be confirmed by bacteriological laboratory examination. Children with primary tuberculosis are generally not infectious.

G. Epidemiology

Each year, there are 8 million people diagnosed with TB and 2 million deaths worldwide. Approximately one-third of the world's population is infected with the tubercule bacillus.

In the United States and New Jersey, the peak of the current epidemic was in 1992. From 1986-1992, the number of active TB cases increased from 22,768 to 26,673 (25%) nationally and from 724 to 983 (36%) in New Jersey. Since 1992, however, the number of active TB cases decreased 43.5% nationally to 15,075 cases and 53.8% in New Jersey to 530 cases. Despite these decreases, the number of active TB cases among the foreign born has increased by over 50% nationally and by over 60% in New Jersey from 1992 – 2002.

A disproportionate number of people who become sick or infected with TB are the most vulnerable in any society: children, the elderly, the poor, the homeless, racial/ethnic minorities, those with coexisting immunosuppressive health conditions and those abusing alcohol and/or illicit drugs.

2) REPORTING CRITERIA AND LABORATORY TESTING SERVICES

A. New Jersey Department of Health and Senior Services (NJDHSS) Case Definition

CASE CLASSIFICATION

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CONFIRMED (Active)

An individual for whom diagnostic evaluations (clinical, epidemiological and laboratory) have been completed and who meets the following criteria:

- A positive Mantoux tuberculin skin test; however, those with immunocompromised illnesses or those very sick with advanced pulmonary disease may have a negative tuberculosis test, **AND**

- Presenting symptoms compatible with active tuberculosis which are improving while receiving anti-tuberculosis treatment with at least two effective drugs, **OR**
- With abnormal, unstable (*e.g.,* worsening or improving) chest radiographs consistent with active tuberculosis while receiving anti-tuberculosis treatment with at least two effective drugs, **AND/OR**

- Laboratory results consistent with active tuberculosis:

  - Isolation of *M. tuberculosis* from a clinical specimen (including rapid identification techniques, e.g., DNA probes and mycolic acids), **OR**
  - Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test, **OR**
  - Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained, **OR**

- If only clinical evidence of current disease is present and the physician has determined that the individual will receive a full course of treatment with two or more anti-tuberculosis medications, the individual can be counted as a case based on provider diagnosis.

PROBABLE
Any individual with diagnosed or suspected tuberculosis, but the diagnostic evaluation (clinical, epidemiological and laboratory) has not been completed.

POSSIBLE
Not used.

C. Laboratory testing Services Available:

The NJDHSS Public Health and Environmental Laboratories (PHEL) perform testing specimens for the following: acid fast bacilli on smear, culture speciation (*M.tuberculosis* complex, *M.avium* complex, *M.gordonae* and *M.kansasii* only), and drug susceptibilities (*M.tuberculosis* complex only). Private physicians and hospitals are required to pay the following fees for processing specimens: AFB only - $30, Culture speciation - $30 and drug susceptibility testing - $30.

In certain situations specimens will be sent to National Jewish Medical Center in Denver, CDC in Atlanta or the Public Health Research Institute in Newark for additional testing or DNA fingerprinting. Additional costs may be applicable for these services. To discuss laboratory services as a whole, or to order these tests, please call 609.292.5849.

3) DISEASE REPORTING AND CASE INVESTIGATION

A. Purpose of Surveillance and Reporting

- To identify suspected TB disease as early as possible and ensure the initiation of effective therapy.
- To complete a thorough interview of the index case to identify the source case and individuals at risk due to exposure and provide a medical assessment and initiate therapy as appropriate for these individuals to reduce the likelihood of progression to active disease or the further spread of infection.
- To conduct a thorough nursing assessment to identify co-existing medical conditions and/or psycho-social issues that may complicate or interfere with the continuity of TB treatment and develop and initiate an individualized patient-centered treatment plan to increase the likelihood of treatment completion (e.g., directly observed therapy, incentives, substance abuse treatment, social service assistance).

- To identify individuals with primary and acquired drug resistance so that medications can be appropriately adjusted.
- To determine those whose treatment regimens are failing, determine the reason(s) and adjust treatment as necessary to facilitate cure.

B. Reporting requirement

Cases of diagnosed or suspected tuberculosis disease (N.J.A.C. 8:57-1.4 and N.J.A.C. 8:57-1.5) and positive laboratory results for tuberculosis (N.J.A.C. 8:57-1.6) shall be reported directly to the NJDHSS. TB case and suspect reports (TB-70) must be sent to NJDHSS within 24 hours of diagnosis and positive laboratory findings of acid fast bacilli on smear and *M.tuberculosis*, *M.leprae* and/or atypical mycobacteria on culture within 5 business days. Report cases to the NJDHSS Tuberculosis Control Program (TB), phone 609.588.7522 and fax 609.588.7562.

C. Local Health Officer Responsibilities

A health officer, or designated representative, will be responsible for the investigation of cases and suspected cases of tuberculosis. See N.J.A.C. 8:57-1.9.

A health officer, or a designated individual, will be responsible to ensure that individuals, who are diagnosed or suspected TB cases and/or exposed to an infectious case of tuberculosis, submit to a medical examination. See N.J.A.C. 8:57-1.11.

A health officer, or a designated individual, will be responsible to ensure that active TB cases-patients complete their medication as prescribed.

A health officer will be primarily responsible for implementing the rules pertaining to the confinement of persons with tuberculosis (N.J.A.C. 8:57-5), if necessary to protect the public health.

4) CONTROLLING FURTHER SPREAD

A. Isolation and Quarantine Requirements (N.J.A.C. 8:57-5)

Patients with infectious pulmonary or suspected pulmonary disease should be hospitalized in a negative pressure room until there are three consecutive negative sputum smears collected on three consecutive days.

B. Protection of Contacts to a Case

Close contacts should be Mantoux tuberculin skin tested with 5 tuberculin units of purified protein derivative (PPD). A reading of 5 millimeters or greater is considered significant (evidence of latent TB infection). All contacts with a significant skin test reaction should have a chest x-ray, submit sputum for laboratory analysis (if symptomatic) and receive a medical evaluation by a doctor to rule out active disease. Any contacts with latent TB infection and a normal chest X-ray should be offered treatment regardless of age.

C. Managing Special Situations

Congregate settings

The risk of transmission in facilities such as jails, state or federal correctional facilities, nursing homes, schools and work sites is especially high due to the potential for increased exposure to individuals with active communicable TB disease. It is important to determine the need for a contact investigation in these settings as soon as possible after the TB case/suspect has been reported. In order to determine the need, a site visit is necessary to validate the information provided by the index case and assess the risk of

transmission due to person, place, time and other environmental factors. Contact the NJDHSS TB Program immediately at 609.588.7522 for guidance on conducting a congregate setting assessment.

HIV Co-Infection

TB is one of the leading causes of death worldwide for HIV-infected individuals. A co-infected person's risk of developing active TB disease rises 7-10% each year. Treatment of individuals with HIV and latent TB infection must be extended to have an equivalent preventive effect against future TB disease. Treatment for active TB disease can be particularly complicated because of drug interactions between first-line anti-tuberculosis drugs and protease inhibitors. It is highly recommended that a consultation be made with physicians at the New Jersey Medical School National TB Center at UMDNJ (Newark) to determine an appropriate treatment regimen. The National TB Center can be reached at 1.800.4TB.DOCS.

Pediatrics

Recently infected children six years of age and younger are at increased risk for rapid progression to active TB disease; therefore, if an initial skin test is negative, children who are close contacts to individuals with infectious TB should be placed on treatment for latent TB infection until a second negative skin test (8-10 weeks after exposure ends) confirms that transmission has not occurred. In addition, any child four (4) years of age or younger found to have a positive skin test through routine screening should have a source case investigation initiated to determine the source of the child's infection. Guidance can be obtained by contacting the NJDHSS TB Program at 609.588.7522.

Pregnancy

Pregnant women who are contacts to TB cases/suspects should be evaluated in the same manner as other contacts. Pregnancy **is not** a contraindication for skin testing or chest radiography. Pregnant women who have latent TB infection should be considered for treatment; however some experts advocate waiting until after the woman gives birth before beginning treatment. Treatment for active disease should not be delayed even during the first trimester of pregnancy, although PZA is not an option for treatment of TB disease during the first trimester so prolonged treatment may be required. Any questions regarding TB and pregnancy should be directed to the New Jersey Medical School National TB Center at UMDNJ (Newark) at 1.800.4TB.DOCS.

D. Preventive Measures

Environmental Measures

Ideally, infectious patients should be placed in a negative pressure room that vents directly to the outside. This will lower the concentration of airborne droplet nuclei that remain in the room. If venting to the outside is impractical, HEPA-filtration can be used to remove droplet nuclei from the air before it is returned to the general circulation system. HEPA-filters must be changed frequently to remain effective. Ultra-violet lighting may also assist in killing tubercle bacilli and should be used in combination with air handling and/or filtration. When not in a hospital, the patient should remain in a well-ventilated space.

Personal Preventive Measures

Infectious patients should be taught to cover their mouths and noses when sneezing or coughing. In addition, when outside of the negative pressure environment, the patient should be given a surgical mask to wear.

Visitors and staff entering the patient's room should wear a NIOSH approved HEPA filtration respirator (N-95) for the entire duration of their visit within the room.

ADDITIONAL INFORMATION

The following websites are available for additional information:

www.state.nj.us/health/cd/tbhome.htm
www.state.nj.us/health/cd/njac857.pdf
http://www.umdnj.edu/ntbcweb/tbsplash.html

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